

REMARKS

Claims 1-3, 5-10, 13-28, and 30-53 are presently pending.

Reconsideration of the application is respectfully requested in view of the following responsive remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

In the Office Action of July 11, 2007 the following actions were taken:

(1) Claims 1-3, 6, 7, and 10 were rejected under 35 U.S.C. 102 as being anticipated by an academic article entitled "Infrared Spectra of Aqueous Solutions. I. Metal Chelate Compounds of Amino Acids" published in the Journal of the American Chemical Society authored by Kazuo Nakamoto, Yukiyoshi Morimoto, and Arthur E. Martell (JACS, 1961 83(22), 4528-4532) (hereinafter "Nakamoto");

(2) Claims 1-3 were rejected under 35 U.S.C. 102 as being anticipated by an academic article entitled "Metal Chelating Tendencies of Glutamic and Aspartic Acids" published in the Journal of Physical Chemistry authored by R. F. Lumb and A. E. Martell (J. Phys. Chem., 1953 57(7), 690-693) (hereinafter "Lumb");

(3) Claims 1-3, 5, 17-19, 27-28, 34-36, 41-45, and 50-53 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 5,504,055 (hereinafter "Hsu");

(4) Claims 1-3, 5, 17, 20-22, 26-28, 34-36, 41-45, and 52-53 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 6,426,424 (hereinafter "Ashmead '424");

(5) Claims 1-3, 5-9, 17-22, 24-28, 43-45, 50-51 and 53 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 4,725,427 (hereinafter "Ashmead '427");

(6) Claims 20-23 was rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu in view of U.S. Pat. No. 6,299,896 (hereinafter "Cooper");

(7) Claims 17-23 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu in view of Cooper;

(8) Claims 1, 13-17, and 30-33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Ashmead '427 in view of an academic article entitled "Production and Utilization of Amino Acids" published in Angewandte Chemie International Edition authored by Yoshiharu Izumi, Ichiro Chibata, and Tamio Itoh (Angew. Chem. Int. Ed. Engl. 17, 176-183) (hereinafter "Izumi"); and

(9) Claims 34, 37-40, 43 and 46-49 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hsu in view of Izumi.

It is respectfully submitted that the presently pending claims be allowed based on the remarks below.

Rejections Under 35 U.S.C. § 102

The Examiner has rejected claims 1-3, 5-10, 17-22, 24-28, 34-36, 41-45, and 50-53 as being anticipated by several references. Before discussing the rejection, it is thought proper to briefly state what is required to sustain such a rejection. It is well settled that "[a] claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987). In order to establish anticipation under 35 U.S.C. 102, all elements of the claim must be found in a single reference. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986), *cert. denied* 107 S.Ct. 1606 (1987). In particular, as pointed out by the court in *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1981), *cert denied*, 469 U.S. 851 (1984), "anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference." "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.* 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989). As the Examiner has rejected the four independent claims, two composition claims and two method claims, a discussion of these claims is provided.

*Composition Claims 1 and 17*

The Examiner has rejected claim 1 and 17 by several general amino acid chelate references; specifically, Lumb, Nakamoto, Hsu, Ashmead '424, and Ashmead '427. However, as previously argued in prior responses, none of the references set forth a non-GMO metal amino acid chelate composition. This being stated, the Applicant previously amended the composition claims to provide that the amino acid chelates have an amino acid to metal molar ratio from about 2:1 to 3:1, and the chelates are fully coordinated. The Examiner has maintained all of the 102 rejections from the prior office action, even though Lumb and Nakamoto do not meet these latter requirements.

Specifically, the Lumb and Nakamoto references clearly identify waters of hydration in their reaction schemes as opposed to a fully coordinated chelate. See Lumb, page 4532,

and Nakamoto, page 693. The Examiner has not provided a reason why the Lumb and Nakamoto rejections have been maintained even though the Applicant has clearly shown that these references do not teach fully coordinated metal amino acid chelates.

Furthermore, as previously argued, there is considerable doubt that either of these references formed chelates at all. Actual experimental conditions that are used to make these “chelates” are sparse at best. Nakamoto merely states “[m]ost of the compounds were prepared by standard procedures,” giving no further guidance. See page 4529, Experimental Section. Additionally, Lumb never states how exactly the chelate forms, instead the reference explains how to calculate the stability constants for the alleged chelates through potentiometric determination. See page 690. In fact, in the abstract, Lumb discloses that the “probable” structures of the chelates are “suggested.” See page 690. It is unclear if the chelates were supposedly formed from the metal chloride and glutamic and aspartic acid solutions. See page 690, col. 2.

In light of the Ashmead ‘427 patent, it is doubtful that Nakamoto or Lumb created a true chelate, since Ashmead states “in order for a true chelate to be formed the mole ratio of protein hydrolysate ligand or amino acid ligand to metal must be at least 2:1 and the reaction conditions must favor the formation of a chelate by the removal of potentially interfering protons.” See col. 5, lines 59-63. Ultimately, it is clear that neither Lumb nor Nakamoto teach fully coordinated chelates, and therefore, the Applicant respectfully requests that these rejections be withdrawn.

The Examiner has responded that the authors have clearly titled their respective publications as metal amino acid chelates, that such was the focus of their studies, and to report otherwise would constitute academic fraud. However, the Applicant submits that the standard to establish a 102 rejection does not depend on the title of the work or the ethical behavior of the author; rather it depends on the explicit teachings of the works. As previously explained, the teachings lack evidence of chelate formation. Additionally, the Applicant submits that the authors were hypothesizing structure.

Additionally, the Examiner has asserted that the burden of establishing the present non-GMO chelate as non-obvious has shifted to the Applicant as the Examiner has provided several references containing metal amino acid chelates. Specifically, the Examiner stated that the Applicant has not “provided a showing of the differences between the prior art metal amino acid chelates and the instantly claimed metal amino acid chelates.” (underlining added)

Even though the Applicant has previously argued that the non-GMO amino acid chelates of the present application are inherently different than those previously disclosed, the Examiner has responded that an amino acid is an amino acid. However, the Applicant is not claiming a simple collection of amino acids but rather a non-GMO metal amino acid chelate. Both independent compositional claims recite “both the amino acid and a source of the metal used to form the amino acid chelate are non-GMO.” In other words, the Applicant submits that it is not enough to find a metal amino-acid reference. The Examiner must show a non-GMO metal amino acid composition. Specifically, the Examiner has alleged that “an amino acid is an amino acid and applicant has not shown a structural difference. Otherwise it would not be the same amino acid.” This is precisely the point that the Applicant is making, i.e., the presently claimed metal amino acid composition is not the same amino acid composition as found in the prior art because there is an inherent compositional difference. To clarify, the Applicant has amended claim 1 to specifically provide that the composition, rather than the chelate molecule *per se*, is non-GMO.

As previously argued, a non-GMO metal amino acid chelate is inherently different than a GMO metal amino acid chelate. The difference relates to the GMO and non-GMO starting materials. Each type has impurities associated with its manufacturing and cultivation processes. Those impurities are not the same. GMO materials by definition contain genetically modified organisms, which are chemically different than their non-genetically modified counterparts. As such, the extraction of an amino acid from those two chemically and structurally different sources would provide a product that is inherently chemically and structurally different since no product is 100% pure and would contain the associated GMO or non-GMO products and impurities. Thus, the composition as a whole can be formulated to be non-GMO. While standard purification techniques should remove a majority of the contaminants, only the methods of the present invention could produce a composition that contains 0% of GMO organisms and associated products. The Applicant contends that the compositions of the present invention are chemically different than those of the prior art since the present method eliminates all GMO material inherently found in previous compositions and methods. The Examiner has previously responded that the impurities referred to by the Applicant are not recited in the claim language. Thus, claim 1 has been amended to require that the chelate is present in a composition that is non-GMO. Thus, the Applicant has recited the lack of impurities via the non-GMO element. This is the very point that Applicant has attempted to convey to the Examiner, the pending claim set requires non-GMO metal amino

acid chelates, and as such, could not contain the impurities that chemically distinguish the present non-GMO metal amino acids from those taught in the prior art.

The Examiner has responded that “it is irrelevant if the genetically modified organisms are chemically and structurally different than their non-genetically modified counterparts. The product is still an amino acid. An amino acid is an amino acid.” See Office Action, page 8. However, the Applicant is not claiming an amino acid, but a non-GMO composition, and as such, the chemical and structural differences between GMO and non-GMO substances are relevant.

The Applicant further renews its argument that the Hsu, Ashmead ‘424, and Ashmead ‘427 references do not teach non-GMO chelate compositions. In fact, the references never mention GMO or non-GMO at all. As these references have publication dates that are well within the time period where genetically modified organisms were prevalent, these patents clearly teach of chelates, in fact, include chelates and related compositions that were likely formed from GMO compositions. The Applicant has claimed a specific narrow class of chelates. The chelates must contain non-GMO components. As the Examiner has not provided a single reference that contains each and every element of the present invention, the Applicant respectfully requests that the Examiner withdraw the current 102 rejections.

#### *Method Claims 34 and 43*

The Examiner has rejected claim 34 and 43 over several general amino acid chelate references; specifically, Hsu, Ashmead ‘424, and Ashmead ‘427. However, as previously argued, none of these references provide a method of preparing or administering a non-GMO metal amino acid chelate composition. The Examiner maintains his contention “that there is nothing to suggest that the methods described in the cited references would direct one of ordinary skill in the art to specifically choose a metal or amino acid from a genetically modified organism.” Likewise, there is nothing to suggest that the methods described in the cited references would direct one of ordinary skill in the art to specifically choose a metal or amino acid from a non-genetically modified organism. In fact, this lack of teaching is precisely the reason the methods of the present invention do not read on the prior art.

The Examiner further elaborates that “[w]ithout clear and convincing evidence, one of ordinary skill in the art would obtain a metal and an amino acid from what the applicant calls a ‘non-GMO’ source, which is inherent in the method.” The Applicant contends that the Examiner has misunderstood the claim. Both independent method claims require an

affirmative non-GMO determination. The Examiner has alleged that since someone skilled in the art “would” obtain from a non-GMO source, the method is anticipated. Although the Applicant does not agree that one skilled necessarily “would” obtain a non-GMO source, whether one could or would is immaterial since the present method claims recite an affirmative non-GMO determination. The fact that a non-GMO source could be used in the prior art does not implicitly or explicitly teach the recited element of an affirmative non-GMO determination. This step is as it is associated with amino acid chelates is not found anywhere in the prior art. At minimum, these method claims should be in allowable condition. The Applicant submits that if the method claims were to be allowed, the Applicant may be willing to cancel the composition claims for pursuit in a separate application.

Additionally, the fact that all of the references cited in the present prosecution are silent as to the use of non-GMO compounds is significant. Even if, as the Examiner has intimated, one skilled in the art would use a non-GMO source, such a supposition does not negate making an affirmative non-GMO determination. In other words, if the sources are non-GMO, no determination would need to be made which further supports patentability of the present method claims.

As previously argued, independent claims 34 and 43 specifically require an affirmative step of making a non-GMO determination for the metal and for the amino acid. Further, the final product must also be non-GMO, which according to the definition in the specification of non-GMO, is quite limiting. Relevant portions of the definitions from the specification are provided herein for the Examiner’s convenience, as follows:

The term “GMO” is an acronym for the term “genetically modified organism(s).”

The term “GMO derivative” applies to any substance produced from, but not containing a genetically modified organism.

The term “non-GMO” herein includes compositions that are not GMOs, and also are not derived from GMOs. In other words, non-GMO compositions are not genetically modified of themselves, and are prepared by processes other than those which include the use of genetically modified organisms. Thus, amino acid chelates prepared in accordance with embodiments of the present invention, such as for human, animal, or foliar application, must not include or be produced with the utilization of genetically modified organisms.

None of the references provided by the Examiner refer to any such affirmative step of determination as required by claims 34 and 43, and further, as the final product must also be non-GMO, there is no teaching or suggestion in any of the references that the chelates described therein unambiguously meet this criteria. As such, the Applicant contends that the two independent method claims and subsequent dependent claims are clearly distinct over the cited references.

The Applicant wishes to remind the Examiner that the product by process inquiry for composition patentability has no relation to the inquiry for the method patentability. The product is not required to be novel for patentability of the method. The method is viewed independent of the product. With this in mind, the Examiner has not provided a reference that provides an affirmative step of non-GMO determination as part of the method in producing a metal amino acid chelate. Therefore, the Applicant respectfully requests that current 102 rejections be withdrawn.

The Examiner has responded that absent a showing that the resources of the prior art are obtained from genetically modified organisms, the Examiner maintains the rejection. However, the Applicant contends that the Examiner is rejecting the present method claims under a composition standard. The Applicant requests that the Examiner consider the method claims independently. Assuming, *arguendo*, that the Examiner is correct in the assumption that the present amino acids are identical to those found in the cited references, does that fact, in and of itself, negate patentability of the present method claims? Of course, the answer is no, as the Applicant is sure the Examiner is well aware. The inquiry as to the method claims is solely whether each step of the method has been shown in a single prior art reference (for a 102 rejection) "in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.* 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989). The Applicant submits that such a standard has not been met by the presently cited references since not a single reference provides the step of making an affirmative non-GMO determination. Furthermore, the Applicant contends that such a determination cannot be inherent as none of the references exclude GMO materials.

As the Applicant has explained the novelty of the independent claims over the prior art, the Applicant respectfully requests that the Examiner withdraw the 102 rejections for the corresponding dependent claims as well.

Rejections Under 35 U.S.C. § 103

The Examiner has rejected claims 1, 13-23, 30-34, 37-40, 43, and 46-49 under 35 U.S.C. 103(a) as being unpatentable over combinations of several references.

Applicant does not deem it necessary to recite the entire case law standard required in order to establish a *prima facie* case of obviousness. However, Applicant, would like to briefly remind the Examiner of the required three criteria for a *prima facie* case of obviousness, namely that the asserted references as modified or combined must: 1) teach or suggest each and every element of the claimed invention; 2) provide sufficient motivation for the modification or combination asserted; and 3) provide a sufficient likelihood of successfully making the modification or combination.

Emphasis on the four independent claims is provided herein, as the Applicants assert that these claims are all patentably distinct over the prior art. Specifically, the Examiner has rejected claims 1, 13-23, 30-34, 37-40, 43, and 46-49 as being obvious in view various combinations of prior art. As the Examiner has rejected the four independent claims, two composition claims and two method claims, a discussion of these claims is provided as follows.

*Composition Claims 1 and 17*

The Examiner has combined Ashmead '427 with Izumo and Cooper with Hsu, to reject claims 1, 13-23, and 30-33. As previously discussed Ashmead '427 and Hsu do not teach a non-GMO chelate composition. The Applicant renews the above arguments with respect to the Ashmead '427 and Hsu references. Additionally, neither Cooper nor Izumi teaches a non-GMO chelate composition. No showing of any such language in any reference in the current office action has been made to make out a *prima facie* case of obviousness. Therefore, the Applicant respectfully requests that the corresponding 103 rejection be withdrawn.

*Method Claims 34 and 43*

The Examiner has combined two references, specifically Hsu and Izumi, to reject claims 34, 37-40, 43, and 46-49. As previously discussed, neither Hsu nor Izumi teach a non-GMO chelate composition. The Applicant renews the previous arguments with respect to the Hsu reference. Additionally, the Examiner has failed to show any such language in any reference in the current office action related to affirmative steps to select non-GMO materials

for use in preparing the non-GMO chelates. As such, no combination references cited by the Examiner teach or suggest every element of the present method claims. Therefore, the Applicant respectfully requests that the corresponding 103 rejection be withdrawn.

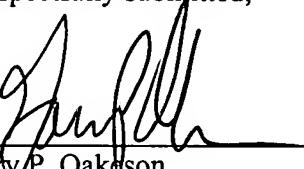
**CONCLUSION**

In view of the foregoing, Applicants believe that claims 1-3, 5-10, 13-28, and 30-53 present allowable subject matter and allowance is respectfully requested. If any impediment to the entry of the present amendment and reconsideration of the claims in view thereof remains which could be removed during a telephone interview, the Examiner is invited to telephone Mr. Gary Oakeson of this office, or in his absence, M. Wayne Western, so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 11<sup>th</sup> day of October, 2007.

Respectfully submitted,



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